K033271
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DYNALOK CLASSIC™ Spinal System
510(k) Summary

October 2003

I. **Company:** Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proposed Proprietary Trade Name:** DYNALOK CLASSIC™ Spinal System

III. **Regulation Name:** Spinal Interlaminal Fixation Orthosis, Spinal Intervertebral Fixation Orthosis, Pedicle Screw Spinal System

IV. **Regulation Number:** 888.3050, 888.3060, 888.3070

V. **Description**

The DYNALOK CLASSIC™ Spinal System consists of a variety of shapes and sizes of plates, bolts, screws, washers, nuts, spacers, CROSSLINK® Plates, and connecting components. The DYNALOK CLASSIC™ Spinal System components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. Additionally, the DYNALOK CLASSIC™ Spinal System may be used in conjunction with TSRH ® Spinal System, CD HORIZON ® Spinal System, and TENOR™ Spinal System.

DYNALOK CLASSIC™ Spinal System implant components are fabricated from medical grade stainless steel. Alternatively, the entire system may be made out of medical grade titanium alloy. **Never use stainless steel and titanium implant components in the same construct.**

To achieve best results and unless stated otherwise in another Medtronic Sofamor Danek document, do not use any of the DYNALOK CLASSIC™ Spinal System components with the components from any other system. (**NOTE:** In addition to the DYNALOK CLASSIC™ rod bolt connectors and bolts, a surgeon may want to connect a spinal rod to CD HORIZON® hooks. The hooks would be applied as stated in the CD HORIZON® Spinal System package insert. However, instead of using the fixed angle CD HORIZON® bone screws or multi axial screws, the DYNALOK CLASSIC™ rod bolt connector and bolt would be substituted in their place. Hooks may only be used posteriorly and provided that the metal alloys are compatible.)

The purpose of this submission is to include an alternative minimally invasive surgical technique to the system.

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VI. Indications for Use

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the DYNALOK CLASSIC™ Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the DYNALOK CLASSIC™ Spinal System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (2) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the DYNALOK CLASSIC™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.
When used as an anterolateral thoracic/lumbar system, the DYNALOK CLASSIC™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

VII. Substantial Equivalence:

No new components were added to the system, as the sole change is the addition of an alternative surgical technique that is left to the discretion of the surgeon. The proposed technique requires no new or modified components, nor does it pose any additional risks. Therefore, the subject submission is substantially equivalent to the predicate DYNALOK CLASSIC™ Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2003

Richard W. Treharne, Ph.D.
Vice President Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K033271
Trade Name: DYNALOK™ CLASSIC Spinal System – Modification of Surgical Procedure
Regulation Number: 21 CFR 888.3070, 21 CFR 888.3060, 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Intervertebral Body Fixation Orthosis, Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: MNI, MNH, KWQ, KWP
Dated: October 8, 2003
Received: October 10, 2003

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033271

Device Name: DYNALOK CLASSIC™ Spinal System

Indications for Use:

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When used as a posterior, non-cervical, non-pedicle screw fixation system, the DYNALOK CLASSIC™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

When used as an anterolateral thoracic/lumbar system, the DYNALOK CLASSIC™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use _____ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)
(Optional 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033271

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